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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,655

09/16/2005

Tetsuya Sakata

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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.

P.O. BOX 2902

MINNEAPOLIS, MN 55402-0902

EXAMINER

SIMPSON, SARAH A

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,655	<b>Applicant(s)</b> SAKATA ET AL.	
	<b>Examiner</b> SARAH A. SIMPSON	<b>Art Unit</b> 4148	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/17/2005; 9/16/2005</u> .                                   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

This office action is in response to application no. 10/549655 filed 9/16/2005.

### *Priority*

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 2003-071516, filed on 3/17/2003.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 1 – 22** are rejected under 35 U.S.C. 102(e) as being anticipated by **Sato et al. (US 7,131,984 B2)**.

**Regarding claim 1**, Sato et al. disclose a lancing device comprising: a moving member (31) for moving a needle in an advancing direction from a standby position to a

puncturing position; and a housing (2) arranged to allow the moving member to move in the advancing direction and in a retreating direction opposite to the advancing direction; wherein the moving member moves in close contact with the housing, wherein the housing includes a first space (30) which is offset in the retreating direction from a portion contacting with the moving member, and a second space (21) which is offset in the advancing direction from the portion contacting with the moving member; wherein the moving member is moved in the retreating direction to be brought to the standby position by a pressure difference produced between the first space and the second space (column 7, lines 4-22).

**Regarding claim 2**, Sato et al. disclose the lancing device according to claim 1, further comprising a fixing means (31a) for fixing the moving member to the housing at the standby position, with an urging force applied in the advancing direction, and also comprising a disengaging means (4) for dissolving the fixing of the moving member, wherein the moving member is moved from the standby position in the advancing direction by the urging force (column 6, lines 56-61).

**Regarding claim 3**, Sato et al. disclose the lancing device according to claim 2, wherein the urging force is applied to the moving member by a resilient member ((34); columns 6-7, lines 62-67, 1-3).

**Regarding claim 4**, Sato et al. disclose the lancing device according to claim 3, wherein the resilient member is a coil spring (34, 17a, 17b) or a bellows (column 7, lines 66-67).

**Regarding claim 5**, Sato et al. disclose the lancing device according to claim 1, wherein the pressure difference causes the moving member to receive suction directed in the retreating direction (abstract).

**Regarding claim 6**, Sato et al. disclose the lancing device according to claim 5, wherein the moving member (31) is moved in the retreating direction (N2) by making pressure in the first space (30) smaller than pressure in the second space (21) beyond a predetermined value (column 8, lines 53-60).

**Regarding claim 7**, Sato et al. disclose the lancing device according to claim 6, wherein the moving member is moved in the retreating direction by making pressure in the first space smaller than atmospheric pressure beyond a predetermined value (column 9, lines 6-16).

**Regarding claim 8**, Sato et al. disclose the lancing device according to claim 5, further comprising a negative pressure generating means for generating a negative pressure in the second space (column 9, lines 6-16).

**Regarding claim 9**, Sato et al. disclose the lancing device according to claim 8, wherein the negative pressure generating means individually generates negative pressure in the first space and the second space (columns 8-9, lines 53-67, 1-16).

**Regarding claim 10**, Sato et al. disclose the lancing device according to claim 8, wherein the negative pressure generating means generates the negative pressure in the first space for applying a suctioning force to the moving member, so that the moving member is moved to the standby position (columns 8-9, lines 53-67, 1-16).

**Regarding claim 11**, Sato et al. disclose the lancing device according to claim 8, wherein the negative pressure generating means comprises a pump (3).

**Regarding claim 12**, Sato et al. disclose the lancing device according to claim 2, wherein air flow into the first space (30) is caused before or on disengaging the moving member (31) by the disengaging means ((4); column 8, lines 54-64).

**Regarding claim 13**, Sato et al. disclose the lancing device according to claim 12, wherein the air flow into the first space is caused when the moving member is disengaged by the disengaging means (column 8, lines 54-64).

**Regarding claim 14**, Sato et al. disclose the lancing device according to claim 13, wherein the disengaging means (4) comprises an operating portion (5) to be operated to cause the disengaging means to act on the engaging means, wherein positional selection of the operating portion determines whether the first space (30) is caused to communicate with outside or not to communicate with the outside (column 9, lines 30-37).

**Regarding claim 15**, Sato et al. disclose the lancing device according to claim 14, wherein the operating portion (5) is movable in the advancing direction and the retreating direction, with part thereof protruding out of the housing, the operating portion including an engaging part (52) accommodated in the housing, wherein the housing is formed with a through-hole (55) for allowing the operating portion to move in the advancing direction and in the retreating direction, wherein the engaging part is used to select between a state in which the engaging part closes the through-hole and a state in which the engaging part does not close the through-hole (column 8, lines 20-24).

**Regarding claim 16**, Sato et al. disclose the lancing device according to claim 1, wherein the second space (21) is provided with a retreating means (13) for moving the needle back in the retreating direction after the needle is brought to the puncturing position (column 7, lines 23-41; fig. 1).

**Regarding claim 17**, Sato et al. disclose a lancing device comprising: a moving member (31) for moving a needle (10b) in an advancing direction from a standby position to a puncturing position; and a housing (2) allowing the moving member to move in the advancing direction and in a retreating direction opposite to the advancing direction, wherein a dividing wall is provided for dividing an inner space of the housing into a first space (30) offset in the retreating direction and a second space (21) offset in the advancing direction (column 7, lines 65-67; wherein a bellow is defined by a dividing wall and the spring may be replaced with a bellow), wherein the moving member (31) is moved in the retreating direction to be brought to the standby position by a pressure difference produced between the first space and the second space (abstract; columns 8-9, lines 53-67, 1-16).

**Regarding claim 18**, Sato et al. disclose the lancing device according to claim 17, wherein the dividing wall includes a bellows (column 7, lines 65-67).

**Regarding claim 19**, Sato et al. disclose the lancing device according to claim 18, further comprising a fixing means (31a) for fixing the moving member (31) to the housing (2) at the standby position, with an urging force applied in the advancing direction, wherein the moving member is moved from the standby position in the advancing direction by the urging force (column 6, lines 56-61).

**Regarding claim 20**, Sato et al. disclose the lancing device according to claim 19, wherein the urging force is applied to the moving member by at least one resilient member (34, 17a, 17b).

**Regarding claim 21**, Sato et al. disclose the lancing device according to claim 20, wherein said at least one resilient member comprises the bellows (column 7, lines 65-67).

**Regarding claim 22**, Sato et al. disclose the lancing device according to claim 21, wherein said at least one resilient member further comprises a coil spring ((34, 17a, 17b); column 7, lines 65-67).

### ***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited for disclosing related limitation of the applicant's claimed and disclosed invention: **Sakata et al. (US 2006/0047220 A1), Matsumoto et al. (US 2006/0129065 A1), Sakata et al. (US 2006/0224171 A1), & Latterell et al. (US 2001/0011157 A1).**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH A. SIMPSON whose telephone number is 571-270-3865. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on 571-272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 4148

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sarah A Simpson/  
Examiner, Art Unit 4148  
28 April 2008

/Terrell L Mckinnon/  
Supervisory Patent Examiner, Art Unit 4148